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(54) **DEFLECTABLE INTERSTITIAL ABLATION DEVICE**

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A61B 18/14 (2006.01)

(52) **U.S. Cl.** **606/41**; 604/95.04; 607/101

(58) **Field of Classification Search** 607/98, 607/115, 116, 96, 99, 100–102, 113; 606/32, 606/33, 39, 41–50, 34; 604/22, 95.04
See application file for complete search history.

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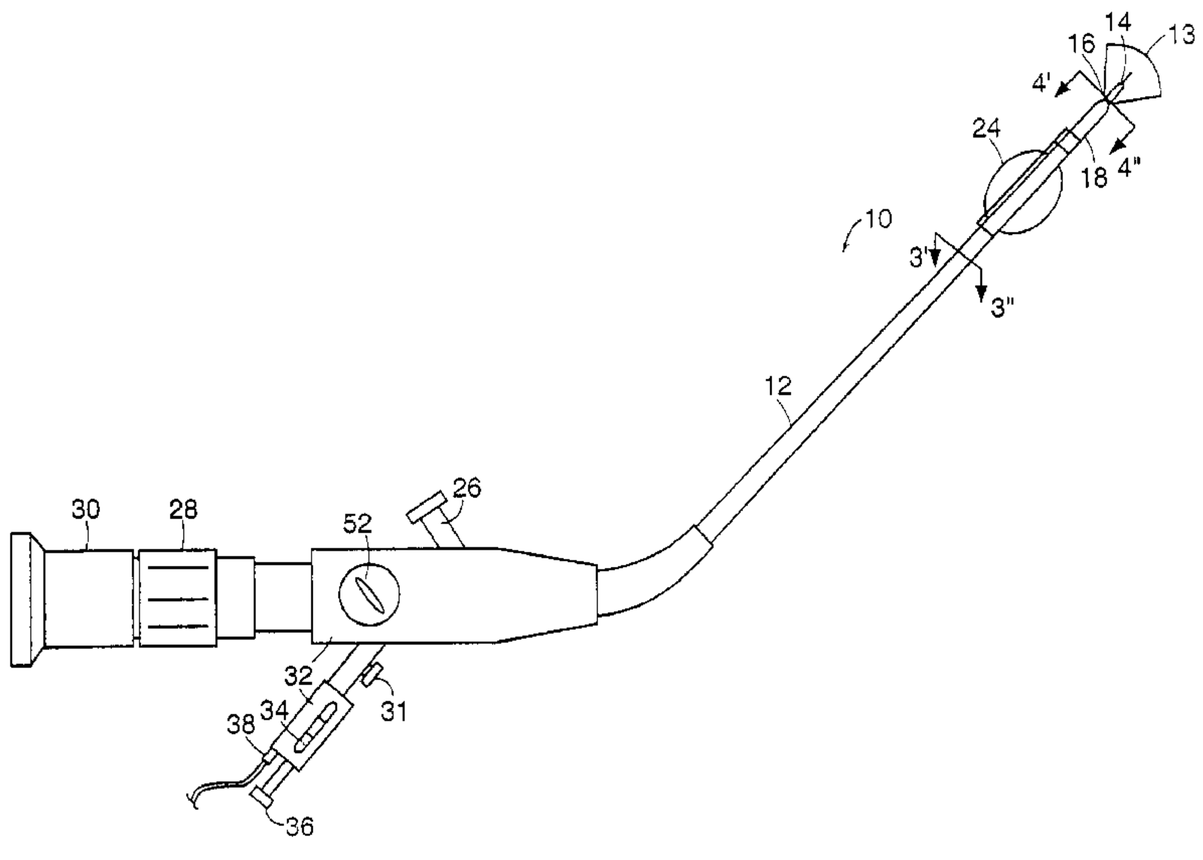
(57) **ABSTRACT**

A deflectable interstitial ablation device includes an elongated housing, an electrode mounted within the elongated housing, a driver coupled to the electrode, an imaging device integrally mounted within the elongated housing and a deflection system disposed within the elongated housing. The elongated housing has a proximal end, a distal end, and a deflectable segment. The electrode is deployable from a first position within the elongated housing to a second position a predetermined distance beyond the distal end of the elongated housing. The electrode further has a flexible portion capable of deflecting with the deflectable segment of the elongated housing, and can be deployed by the driver with a sufficient force such that penetration of the urethral wall occurs in a single motion. The imaging device further has a flexible portion capable of deflecting with the deflectable segment of the elongated housing. The deflection system has a proximal end in communication with a steering mechanism, for controllably deflecting the deflectable segment of the elongated housing by any angle. The deflection of the deflectable segment allows deflection of the electrode and the imaging device, thus facilitating proper placement of the electrode.

20 Claims, 6 Drawing Sheets



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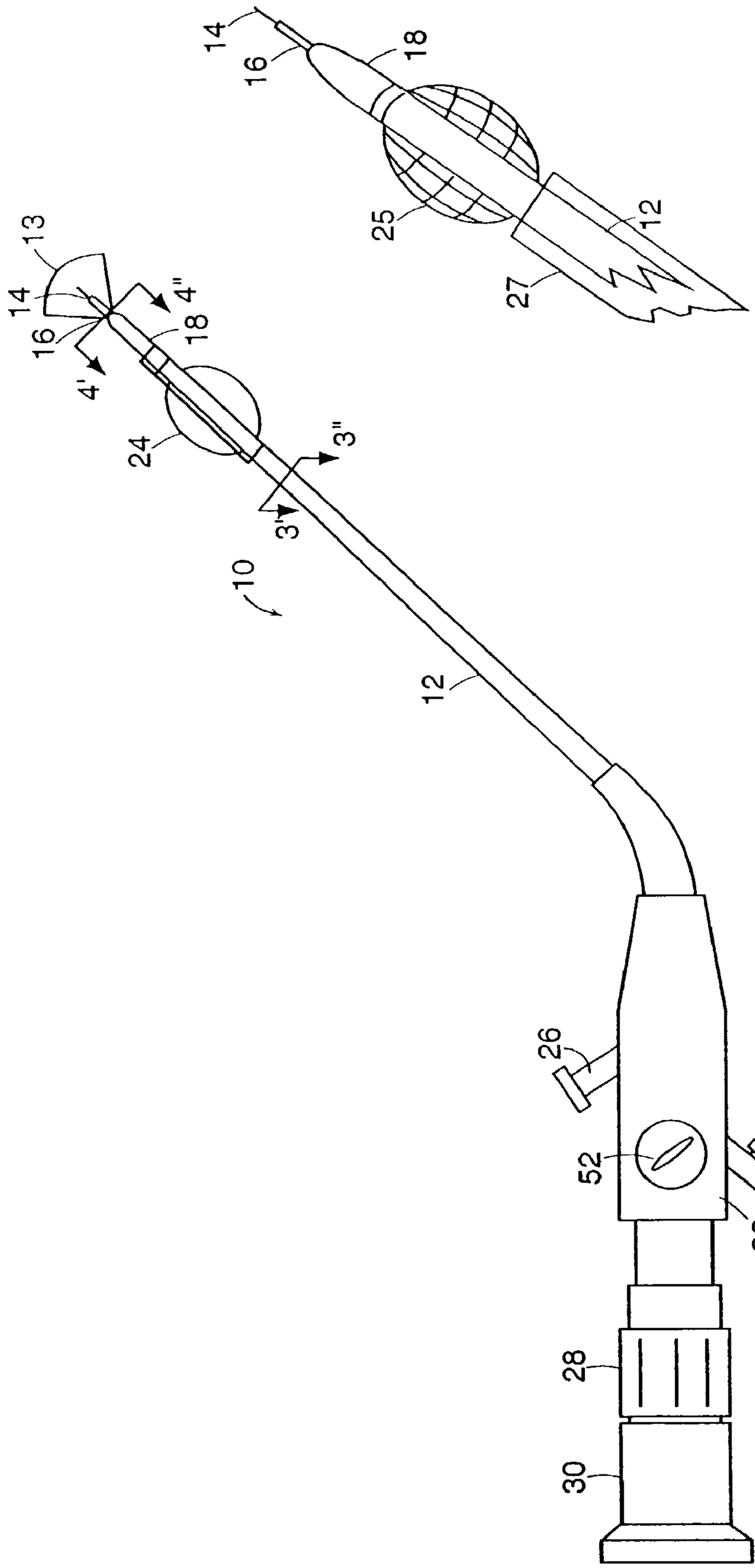

FIG. 1B

FIG. 1A

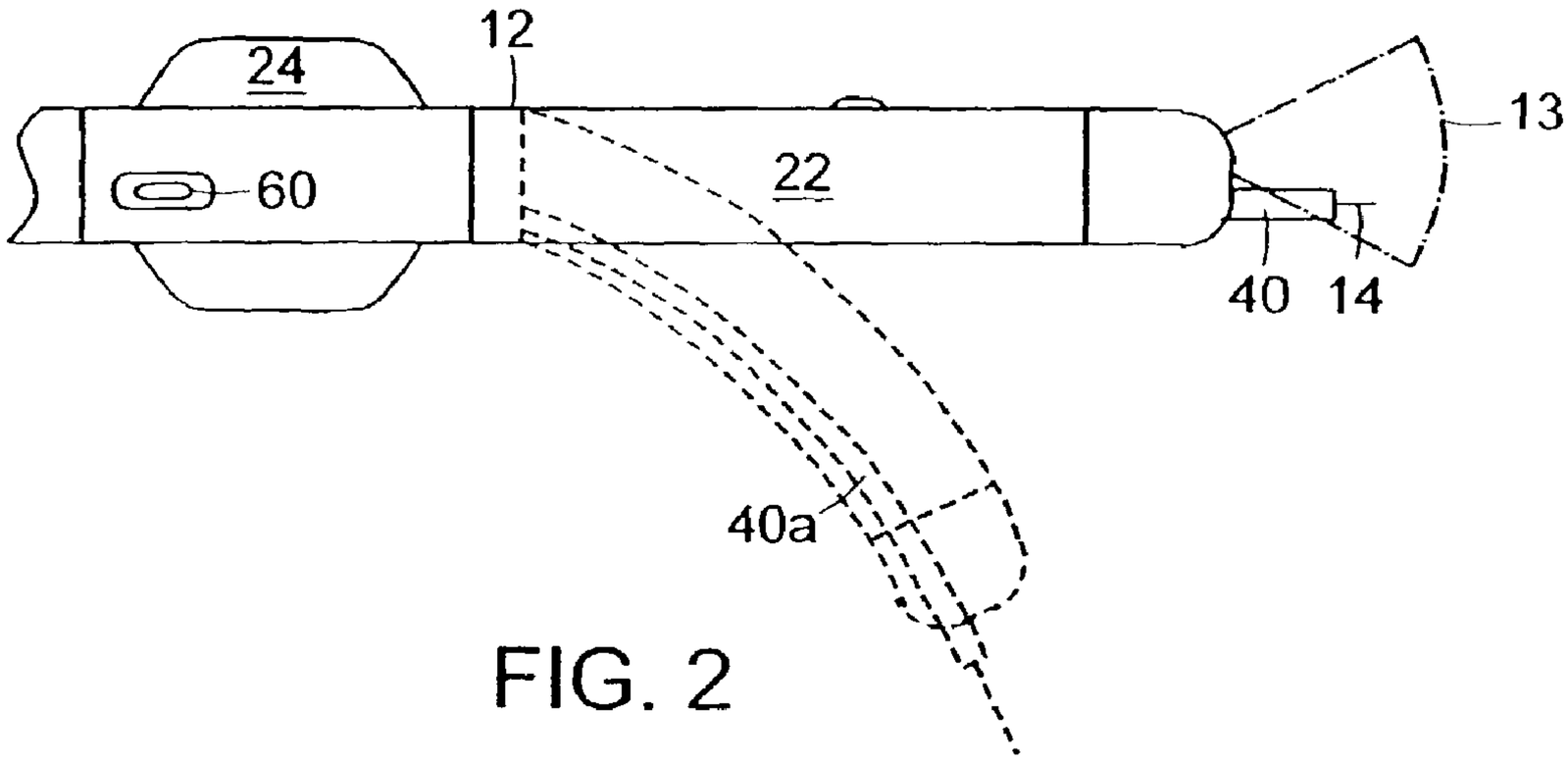

FIG. 2

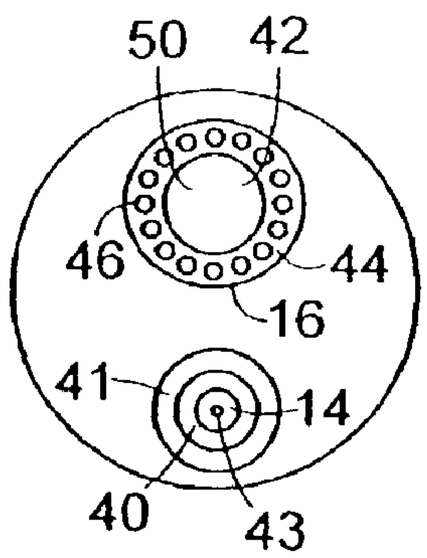

FIG. 3

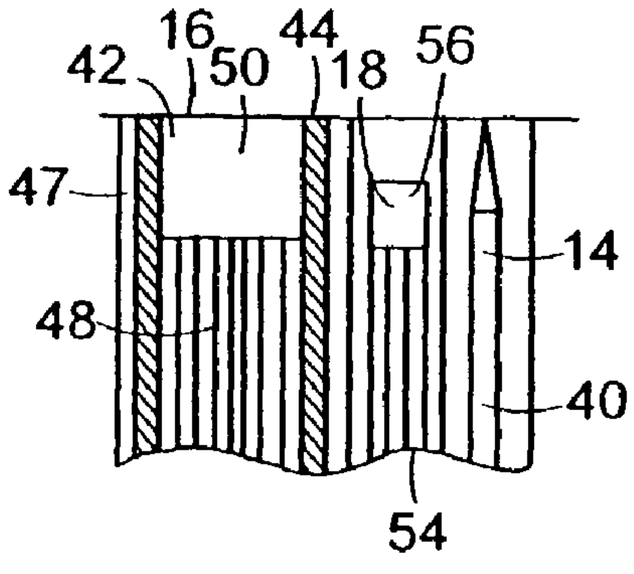

FIG. 4

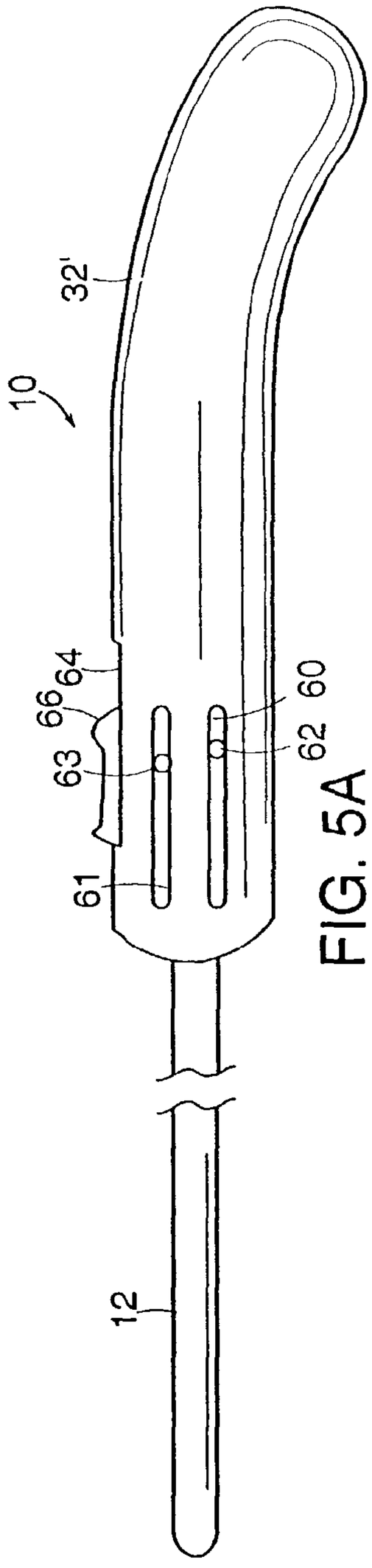

FIG. 5A

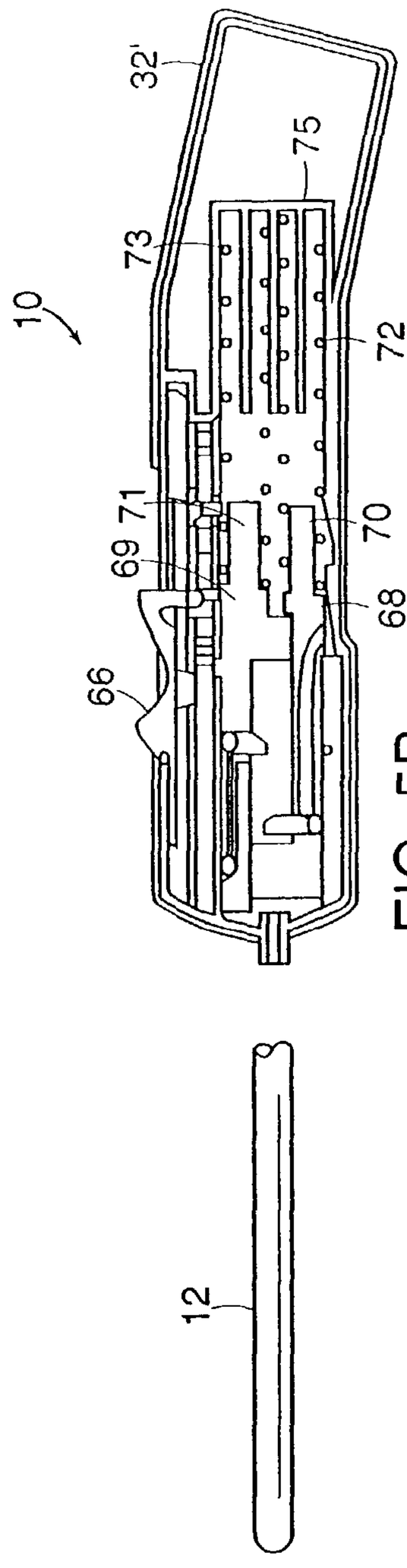

FIG. 5B

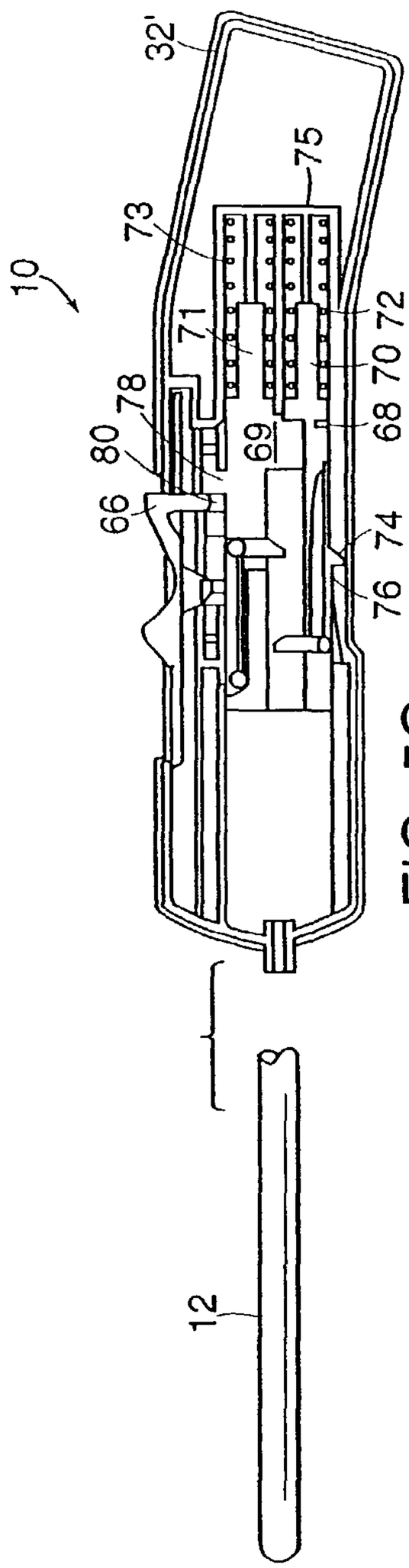

FIG. 5C

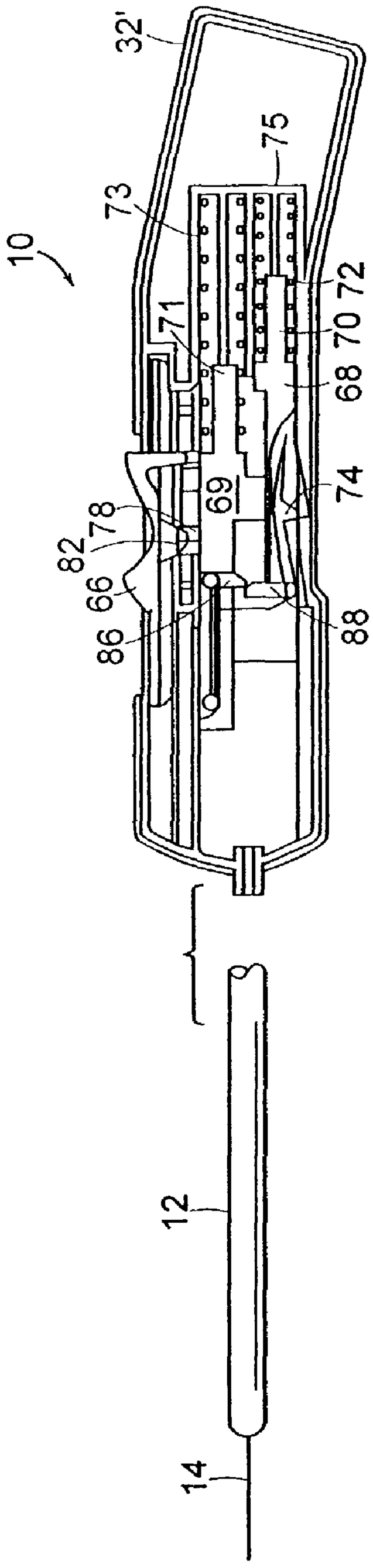
10
32'
73
75
71
72
70
68
74
69
78
82
66
86
88
12
14

FIG. 5D

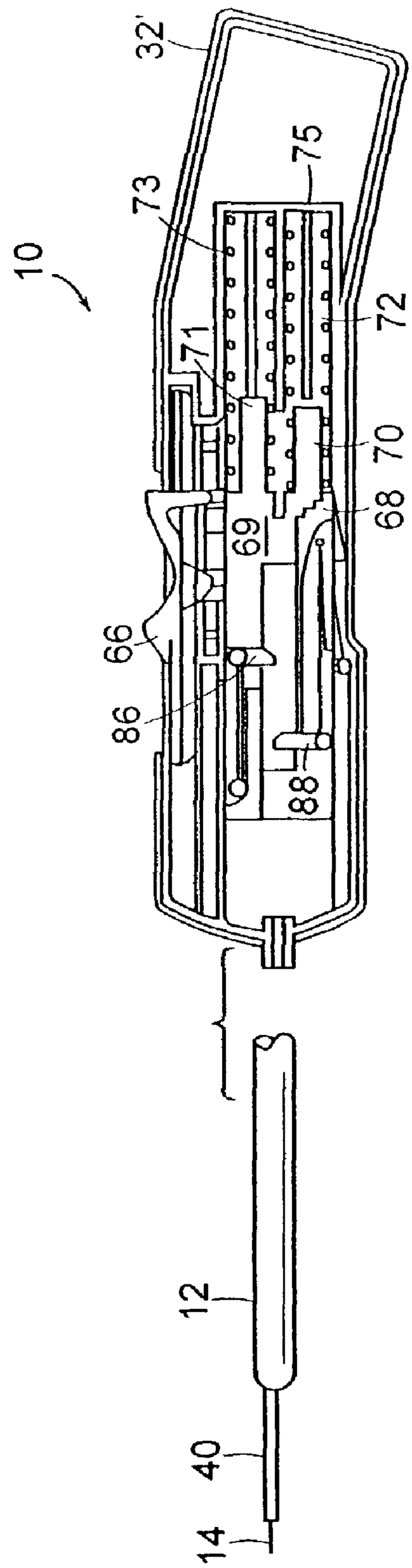
10
32'
73
75
71
72
70
68
69
66
86
88
12
40
14

FIG. 5E

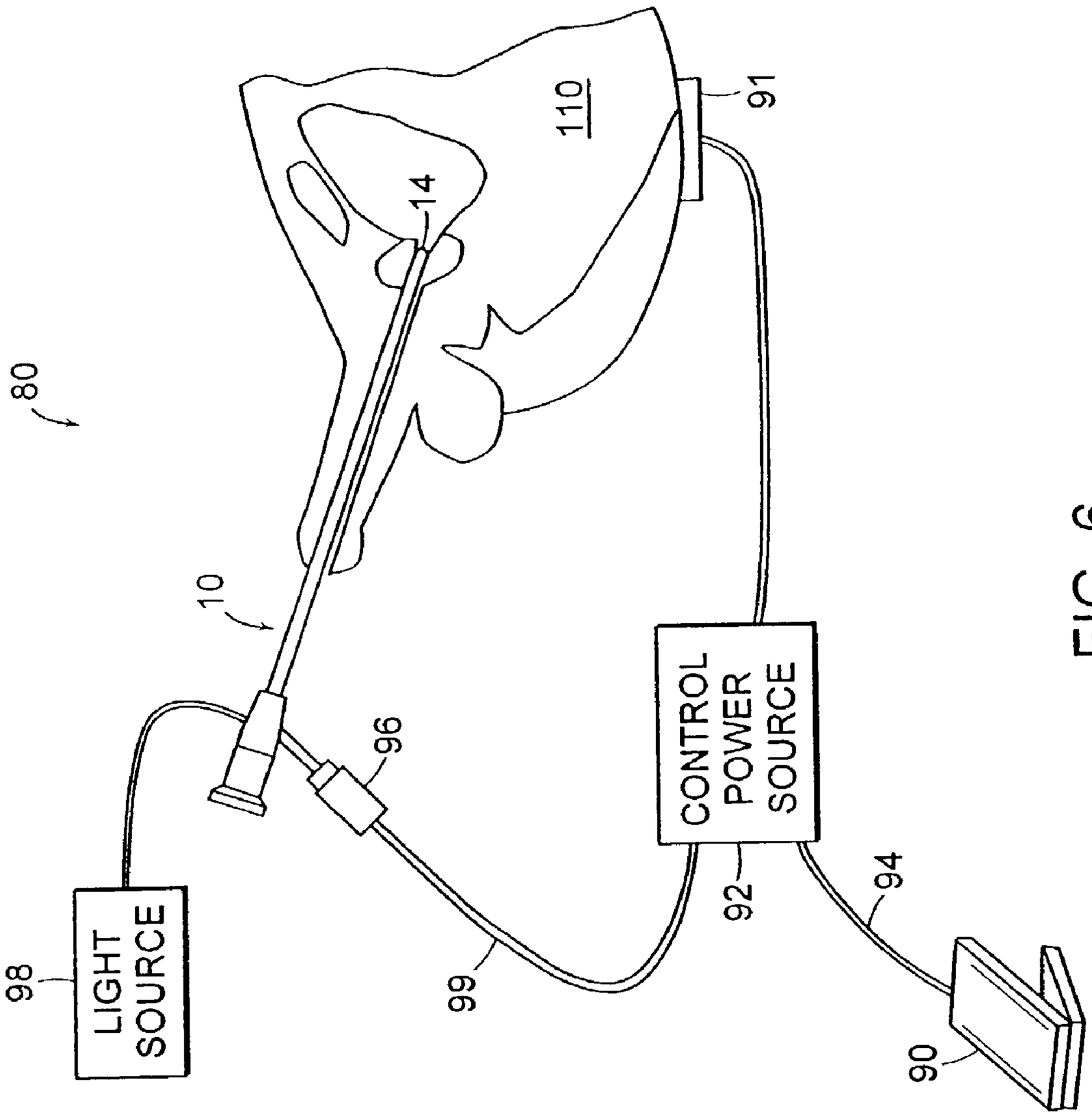
80
10
14
110
91
96
98
LIGHT SOURCE
99
CONTROL POWER SOURCE
92
94
90

FIG. 6

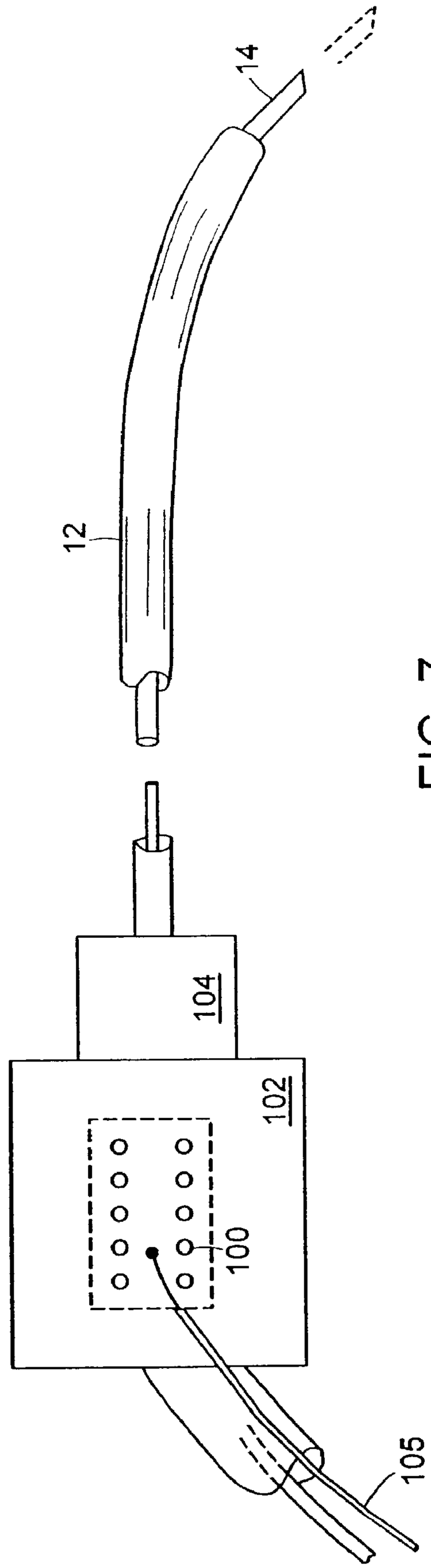

FIG. 7

DEFLECTABLE INTERSTITIAL ABLATION DEVICE

This application is a continuation of U.S. patent application Ser. No. 10/004,759, filed on Dec. 4, 2001, now U.S. Pat. No. 6,482,203, which is a continuation of U.S. patent application Ser. No. 09/661,835, filed on Sep. 14, 2000, now U.S. Pat. No. 6,352,534, which is a continuation of U.S. patent application Ser. No. 08/940,519, filed on Sep. 30, 1997, now U.S. Pat. No. 6,238,389. The disclosures of each of the above applications are incorporated by reference in their entirety.

FIELD OF THE INVENTION

The invention relates to an interstitial ablation device and method for performing tissue ablation, and in particular, to an improved interstitial ablation device providing enhanced electrode placement and control.

BACKGROUND

Ablation devices can be used to treat tumors in the body. In particular, ablation devices can be used to treat benign prostatic hypertrophy or hyperplasia (BPH), a condition resulting in an enlargement of the prostate gland. This is a common medical problem typically experienced by men over 50 years of age. Hyperplastic enlargement of the prostate gland often leads to compression of the urethra, which results in obstruction of the urinary tract.

An ablating needle can be used with a cystoscope to treat BPH by ablating a prostatic adenoma, which is a benign tumor inside the prostate. To perform the ablation procedure, a physician inserts a distal end of the cystoscope into the urethra of a patient while viewing the advance through an eye piece of the cystoscope. The needle electrode is also introduced into the urethra through a working channel of the cystoscope. The cystoscope and the needle electrode are typically introduced inside the urethra sequentially. The distal end of the needle electrode is positioned adjacent the prostate near the prostatic adenoma. The physician then causes the needle electrode to penetrate the urethral wall, such that it is positioned inside the prostatic adenoma. Radiofrequency (RF) energy is applied to the needle electrode to coagulate tissue surrounding the electrode. Coagulation causes necrosis of the prostatic adenoma, resulting in atrophy of the prostate and a reduction in the compressive forces that interfere with urine flow through the urethra.

During the ablation procedure, it is important that the needle electrode be positioned precisely, because inaccurate electrode placement can cause incontinence in the patient. Visualization is typically provided by inserting the needle electrode through a cystoscope. One disadvantage of the ablation device insertable through a cystoscope is that it is difficult to feed the device through a working channel of the cystoscope and requires a lot of juggling which can make accurate placement of the needle electrode difficult. Moreover, it is often difficult to observe the distal tip of the needle electrode as the electrode penetrates the urethral wall, because the distal end of the electrode is typically deflected in order to penetrate the urethral wall while the viewing device itself does not deflect along with the needle electrode.

Existing interstitial ablation systems are also uncomfortable for the patients and cumbersome for the physician performing the procedure. Most cystoscopes and ablation systems integrating imaging devices tend to be rigid and uncomfortable for patients when inserted through a body lumen such as the urethra. The systems also have numerous

knobs and dials that the physician must adjust for controlling needle deployment, fluid introduction, and application of RF energy.

Thus, there remains a need for an interstitial ablation device that provides accurate electrode placement and better control of the electrode, reduces patient discomfort and simplifies the process of performing ablation.

SUMMARY OF THE INVENTION

In one aspect, the invention features a deflectable interstitial ablation device. In one embodiment, the device includes an elongated housing, an electrode mounted within the elongated housing, a driver coupled to the electrode, an imaging device integrally mounted within the elongated housing, and a deflection system disposed within the elongated housing. The elongated housing has a proximal end, a distal end, and a deflectable segment. The electrode is deployable from a first position within the elongated housing to a second position a predetermined distance beyond the distal end of the elongated housing, and has a flexible portion capable of deflecting with the deflectable segment of the elongated housing. The driver exerts a force sufficient to drive the electrode from the first position to the second position in a single motion. The imaging device has a flexible portion capable of deflecting with the deflectable segment of the elongated housing. The deflection system controllably deflects the deflectable segment of the elongated housing to a desired angle. The deflection system has a proximal end in communication with a steering mechanism.

In one embodiment, the imaging device includes a plurality of illumination optical fibers and a plurality of viewing optical fibers extending from the proximal end to the distal end of the elongated housing. The viewing optical fibers can comprise a fused bundle of viewing optical fibers surrounded by illumination optical fibers, wherein the viewing optical fibers are in communication with a lens disposed at the distal end of the elongated housing. In another embodiment, the electrode is a hollow needle electrode and an insulation sheath surrounds the needle electrode. The needle electrode and the insulation sheath are individually and slidably mounted inside the elongated housing, such that the insulation sheath is capable of covering a proximal portion of the needle electrode which extends beyond the distal end of the elongated housing. In still another embodiment, the driver coupled to the electrode can exert a force within the range of ¼ lb to 1 lb to drive the electrode from the first position to the second position in a single motion.

In another embodiment, the device includes an elongated housing, an electrode mounted within the elongated housing, an imaging device integrally mounted with the elongated housing, a deflection system disposed within the elongated housing, and a foot pedal for deploying the electrode.

In another aspect, the invention features a method for treating tissue. A deflectable interstitial ablation device is inserted into a body lumen which provides access to the tissue to be treated. The deflectable interstitial ablation device includes an elongated housing having a deflectable segment, a deployable electrode mounted within the elongated housing, a driver coupled to the electrode for exerting a force to drive the electrode, an imaging device integrally mounted with the elongated housing, and a deflection system disposed within the elongated housing. The distal end of the elongated housing is positioned near the tissue. The deflectable segment of the elongated housing is deflected toward the tissue, thereby deflecting the electrode and the imaging device toward the tissue along with the deflectable segment. The electrode is

deployed to penetrate a wall of the lumen and to position a distal end of the electrode adjacent the tissue. Radio frequency energy is applied to the electrode in an amount and for a duration sufficient to ablate the tissue.

In one embodiment, an insulation sheath is deployed to cover a proximal portion of the deployed electrode to protect the wall of the lumen from directly contacting the needle electrode during the treatment. In another embodiment, a balloon disposed on a body of the elongated housing of the deflectable interstitial ablation device is inflated to secure the position of the elongated housing inside the lumen. In yet another embodiment, a basket disposed on a body of the elongated housing of the deflectable interstitial ablation device is expanded to secure a position. In still another embodiment, the distal end of the elongated housing is connected to an actuator in communication with a foot pedal and the foot pedal is depressed to deploy the electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described with particularity in the appended claims. The above and further advantages of this invention may be better understood by referring to the following description taken in conjunction with the accompanying drawings.

FIG. **1**A shows a side view of a deflectable interstitial ablation device according to one embodiment of the invention.

FIG. **1**B shows a portion of the deflectable insterstital ablation device having a basket for maintaining the placement of the device in a body lumen, according to one embodiment of the invention.

FIG. **2** illustrates a deflecting segment of the deflectable interstitial ablation device of FIG. **1**A.

FIG. **3** shows a cross sectional view of the deflectable interstitial ablation device of FIG. **1**A cut through lines **3'-3"**.

FIG. **4** shows a cross sectional view of a distal end of the deflectable interstitial ablation device of FIG. **1**A cut through lines **4'-4"**.

FIG. **5**A is a side view of a kinetically deployable needle electrode according to one embodiment of the invention.

FIG. **5**B is a cross sectional view of the kinetically deployable needle electrode of FIG. **5**A prior to deployment.

FIG. **5**C is a cross sectional view of the kinetically deployable needle electrode of FIG. **5**A in a loaded position.

FIG. **5**D is a cross sectional view of the kinetically deployable needle electrode of FIG. **5**A with the needle electrode deployed.

FIG. **5**E is a cross sectional view of the kinetically deployable needle electrode of FIG. **5**A with the needle electrode and the insulation sheath deployed.

FIG. **6** shows a transurethral interstitial ablation system employing a foot pedal according to one embodiment of the invention.

FIG. **7** shows an actuator for deploying a needle electrode according to one embodiment of the invention.

DETAILED DESCRIPTION

Referring to FIGS. **1**A and **4**, a deflectable interstitial ablation device **10** includes an elongated housing **12**, an electrode **14** extending within the elongated housing **12**, an imaging device **16** integrally mounted with the elongated housing **12** and a deflection system **18** disposed within the elongated housing **12**. The electrode **14** can comprise a needle electrode having a sharpened tip, or an electrode having a blunt tip. The elongated housing **12** has a proximal end, a distal end and a deflectable segment **22** further as further shown in FIG. **2**. The elongated housing **12** can be constructed to be flexible so that the housing **12** may be inserted into the urethra without much discomfort. In one embodiment, the housing **12**, can be, for example, a flexible multi-lumen catheter. In another embodiment, the housing **12**, can be, for example, a substantially rigid, single lumen catheter having a deflectable segment **22**. In one detailed embodiment, the housing **12** can have a diameter from about 15 to 16 French. It is to appreciated that the diameter of the housing **12** can vary depending on the intended use of the ablation device **10**.

In order to provide accurate placement of the electrode **14** inside the urethra, the present invention further provides means for stabilizing the position of the device **10** before deploying the electrode **14**. In one embodiment, the elongated housing **12** of the invention includes a balloon **24** for securing the position of the device **10** while the electrode **14** is deployed at the ablation site. The elongated housing **12** includes a fluid port with a luer fitting **26** for introducing a fluid such as, for example, air or water for inflating the balloon **24**. The fluid enters the balloon **24** through an inflation sleeve further shown in FIG. **2** to inflate the balloon **24**. Another advantage provided by the balloon **24** is that the balloon **24** can block the blood vessels on the urethral wall and slow down heat conduction provided by the blood vessels. In one embodiment, the balloon **24** is compliant enough to fit inside the urethra. In one detailed embodiment, the balloon is constructed of latex or silicone. The diameter of the inflated balloon, in one embodiment, can be about 30 French.

In another embodiment, as shown in FIG. **1**B, the elongated housing **12** can include a basket **25** to stabilize the device **10** position during deployment of the electrode **14**. The basket **25** can comprise a wire mesh attached to an outer surface of the housing **12** surrounding the electrode **14**, the imaging device **16** and the deflection system **18**. The housing **12** can further be surrounded by an elongated sheath or catheter **27** such that the wire mesh comprising the basket **25** remains retracted during placement of the device and expands into the basket **25** shown in FIG. **1**B to secure the position and placement of the electrode **14** after the electrode **14** has been exposed.

As shown, the proximal end of the elongated body **12** is in communication with a detachable eye piece coupler **28**. A detachable eye piece **30** is coupled to the eye piece coupler **28**, and the physician observes insertion of the device **10** into the urethra and the electrode **14** deployment by looking into the eye piece **30**.

The proximal end of the elongated body **12** is also in communication with a handle **32**. The handle **32** includes a slide member **34** for controlling deployment of the electrode **14**. In one embodiment, the handle **32** can include two slide members (not shown), one for controlling the movement of the electrode **14** and the other for controlling the movement of the insulation sheath **40**. In another embodiment, the slide member **34** can control the movement of the electrode **14** and the insulation sheath **40** secured to the electrode **14**, to expose a predetermined amount of the electrode **14**. As shown, the handle **32** also includes an electrical connector **38** for coupling the proximal end of the electrode **14** to a power source (not shown). In a preferred embodiment, the power source is an RF generator, however it is to be appreciated that other energy sources can be used, such as a microwave generator. The handle **32** further includes a luer port **36** for injecting fluid and an irrigation port **31** for removing fluid. In one embodiment, the fluid can be a conductive fluid for improving ablation procedures. Conductive fluids, can include, for example, saline and lydocaine. The use of a conducting fluid

prevents desiccation of tissue and prevents an increase in the impedance during the ablation procedure.

Referring to FIG. **2**, the electrode **14** can be deployable from a first position within the elongated housing **12** to a second position beyond the distal end of the elongated housing **12** as shown. In one embodiment, the electrode **14** deploys to a predetermined distance beyond the distal end of the elongated housing **12**. It is to be appreciated that the distance the electrode **14** deploys can vary depending on the intended application. As shown, the electrode **14** also has a flexible portion **40***a* which deflects along with the deflectable segment **22** of the elongated housing **12**. In one detailed embodiment, the deflectable segment **22** is located at the distal end of the elongated housing **12** and has a dimension of from about 2.5 cm to about 4.5 cm measured from the distal end of the housing **12**. It is to be appreciated that the length of the deflectable segment **22** can fall outside of the above range, depending on the intended application of the device **10**. In one embodiment, the dimension and position of the flexible portion **40***a* of the electrode **14** corresponds to that of the deflectable segment **22** of the elongated housing **12**. Referring to FIG. **2**, illustrated in phantom in a deflected position, is the deflectable segment **22** and electrode's flexible portion **40***a* at the distal tip of the elongated housing **12**.

Referring to FIGS. **2** and **3**, the electrode **14** can be a needle electrode surrounded by an insulation sheath **40**. The needle electrode **14** and the insulation sheath **40** are placed inside an electrode guide tube **41** disposed inside the elongated housing **12**. The insulation sheath **40**, for example, may be constructed from an insulating polymer material such as polyimide. In another embodiment, the needle electrode **14** can be coated with an insulator, such as Teflon or ceramic. The needle electrode **14** and the insulation sheath **40** can be individually and slidably mounted inside the elongated housing **12**, such that the insulation sheath **40** is capable of covering a proximal portion of the needle electrode **14** extending beyond the distal end of the elongated housing **12**. By adjustably covering a proximal portion of the electrode **14** with the insulation sheath **40**, the physician can control the amount of electrode **14** that is exposed, and thus control the conductive region and consequently, the size of the ablation area. This feature is important in transurethral interstitial ablation of prostate tissue, because urethral walls can be protected from being ablated during the procedure. Alternatively, the insulation sheath **40** can be fixed to a proximal portion of the needle electrode **14** and the needle electrode **14** can be slidably mounted inside the elongated housing **12**. In another embodiment, as shown in FIG. **3**, the electrode **14** can comprise a hollow electrode **14** including a passageway **43**. In one embodiment, the hollow electrode **14** has an inner diameter of approximately 0.011 inches and an outer diameter of approximately 0.02 inches. The insulation sheath **40** has an outer diameter of approximately 0.03 inches and an inner diameter of about 0.025 inches. The electrode guide tube **41** has an inner diameter of about 0.039 inches. It is to be appreciated that the above dimensions are illustrative, and are not intended to be restrictive, as other dimensions can be used depending in whole or in part, on the intended application of the device.

Referring to FIGS. **3** and **4**, the imaging device **16** disposed inside the elongated housing **12** includes a illumination region **44** and a viewing region **42**. Both regions **42** and **44** can include a plurality of optical fibers **46** extending from the proximal end to the distal end of the elongated housing **12**. In the embodiment of FIGS. **3** and **4**, the illumination region **44** includes a plurality of optical fibers **46** in communication with a light source (not shown) at a proximal end. The plurality of optical fibers **46** surrounds the viewing region **42**. The viewing region **42** can include a fused bundle of optical fibers **48** in communication with an objective lens **50** at the distal end for focusing an image. An example of the objective lens **50** is a gradient index (GRIN-self) objective lens having a diameter of about 0.039 inches. The illumination region **44** and the viewing region **42** may be arranged in other ways and may comprise optical components other than or in addition to those described above. In other embodiments, other imaging devices can be used for viewing the area of tissue in question. In one embodiment, the imaging device **16** is surrounded by an outer sheath comprising a polymeric material **47**. In another embodiment, the imaging device **16** is disposed inside the elongated housing **12** without an outer sheath. In one detailed embodiment, the imaging device **16** has a viewing angle **13** of about 70 degrees, as shown in FIGS. **1** and **2**. It is to be appreciated that the viewing angle **13** can be greater or less than 70 degrees depending in whole or in part, on the intended application of the device.

Referring to FIGS. **1** and **4**, the deflection system **18** controllably deflects the deflectable segment **22** by an angle of up to 180 degrees in one direction and 180 degrees in the opposite direction with respect to the longitudinal axis of the elongated housing **12**. In one embodiment, the deflection system **18** includes a flexible wire **54** extending from the proximal end to the distal end of the elongated housing **12** and a flat spring **56** in communication with the flexible wire **54** disposed at the distal end of the elongated housing **12**. The proximal end of the flexible wire **54** is in communication with a steering mechanism **52**, shown in FIG. **1**A as mounted on the handle **32**. The steering mechanism **52** can pull the flexible wire **54** and cause the flat spring **56** to gradually deflect toward a direction to which the wire **54** is pulled. Details of the steering mechanism are described in U.S. Pat. No. 5,273,535, which is incorporated herein by reference. In one detailed embodiment, the deflection system **18** has an outer diameter of approximately 0.02 inches. It is to be appreciated that the diameter of the deflection system **18** can vary depending in whole or in part, on the intended application of the device.

Referring to FIGS. **5**A-**5**E, in another embodiment, the deflectable interstitial ablation device **10** further includes a driver **75** located in the handle **32** and coupled to the electrode **14** for kinetically deploying the electrode **14**. In this embodiment, the electrode **14** can be a needle electrode having a sharpened tip. The driver **75** exerts a force sufficient to deploy the electrode **14** from inside the elongated housing **12** to a position beyond the distal end of the elongated housing **12** in a single motion. In one embodiment, the force of deployment can range from about ¼ lb to about 1 lb. A force in this range is sufficient to cause the electrode **14** to penetrate the urethral wall in a single motion. Kinetic deployment which permits sudden and high speed deployment facilitates electrode penetration through the urethral wall, reducing patient discomfort and improving the accuracy and control of needle deployment. In the present embodiment, such kinetic deployment is achieved by employing a driver **75** comprising a spring-operated actuating mechanism.

Referring to FIG. **5**A, the handle **32'** includes slots **60** and **61** having levers **62** and **63**, respectively, and a recess **64** having an actuator **66** on an outer surface of the handle **32'**. Referring to FIGS. **5**B to **5**E, contained within the housing **32'** are slide members **68** and **69**. The slide member **68** is connected to the insulation sheath **40**, and the slide member **69** is connected to the electrode **14**. The lever **62** is connected to the slide member **68** and the lever **63** is connected to the slide member **69**. Reduced proximal sections **70** and **71** of the slide

members **68** and **69** are received within spring coils **72** and **73**, respectively. The actuator **66** is operatively coupled to the slide member **69**. In this embodiment, the electrode **14** and the insulation sheath **40** are sequentially propelled.

Referring to FIG. **5**C, prior to inserting the elongated sheath **12** inside the body, the device **10** is loaded by pulling the levers **62** and **63** in the proximal direction. As the lever **62** is pulled in the proximal direction, a projection **74** on the slide member **68** slides over and catches the distal surface of a catch or stop **76**, and as the lever **63** is pulled, a projection **78** of the slide member **69** catches on a stop **80**. Once the elongated sheath **12** is properly placed inside the body and the deflectable segment **22** is deflected by a desired angle, the needle electrode **14** and the insulation sheath **40** are deployed by pulling the actuator **66** proximally and then down.

Referring to FIG. **5**D, as the actuator **66** is pushed down, the stop **76** moves allowing the slide member **69** to move distally until the projection **78** is restrained by a stop **82**. The needle electrode **14** is propelled forward as the sliding member **69** is moved by the force from the coiled spring **73**. Referring to FIG. **5**E, as the slide member **69** moves forward, and just before the end of its distal movement as the projection **78** reaches the stop **82**, a trigger member **86** on the slide member **69** contacts a release member **88**. Movement of the release member **88** causes the projection **74** to disengage from the stop **76**, such that the slide member **68** is propelled forward by the force of the coiled spring **73**. As the slide member **68** propels forward, the insulation sheath **40** propels beyond the distal end of the elongated housing **12** covering a predetermined portion of the needle electrode **14**.

Referring to FIG. **5**D, in one embodiment, only the needle electrode **14** is propelled with a spring operated actuating mechanism, while the insulation sheath **40** is glided over the needle electrode **14**. Once the needle electrode **14** has penetrated the urethral wall, gliding the insulation sheath **40** over the needle electrode **14** can be easily achieved without causing much discomfort to the patient.

In one embodiment, depth of needle electrode **14** penetration is controllable, such that different locations within the prostate can be reached by the needle electrode **14**. In one detailed embodiment, the steering mechanism **52** described above can provide depth control. For deeper penetration, the electrode **14** tip can be deflected closer to 90 degrees, whereas for shallow penetration, the needle electrode **14** tip can be deflected by a smaller angle, such as, for example, 45 degrees. In another detailed embodiment, depth of electrode **14** penetration is adjustable using a slide member on the handle **32**, which controls movement of the needle electrode **14** relative to the elongated housing **12**. In this embodiment, maximum penetration depth may be fixed by placing a stop inside the handle **32**.

Referring to FIG. **6**, in another embodiment, the electrode **14** can be kinetically deployed using a foot pedal. As shown, the interstitial ablation system **89** includes a foot pedal **90**, a control and power source module **92**, an actuator, a light source **98**, the deflectable interstitial ablation device **10**, and a return electrode **91**. The light source **98** supplies light to the illumination region **44** of the imaging device **16**, described above in FIGS. **3** and **4**. As shown in this embodiment, the return electrode **91** is placed on the patient **110**. The foot pedal **90** is coupled to the control and power source module via a cable **94**, and the control and power source module **92** is coupled to the actuator **96** via a cable **99**. In operation, a physician performing an ablation procedure properly places the ablation device **10** inside the patient's body, then steps on the foot pedal **90** to deploy electrode **14**, leaving his or her hands free to perform other functions. Additional features such as application of fluid to a treatment site, application of energy to the electrode **14**, and the triggering temperature measurement means at the distal end of the electrode **14** may also be activated using the pedal **90**. In one embodiment, the interstitial ablation system **89** can include several foot pedal actuators for performing each of these functions. In another embodiment, the interstitial ablation system **89** can include only one foot pedal used to activate multiple functions. In this embodiment, the control module **92** may be programmed to control the order of the performance of each function.

Referring to FIG. **7**, shown is the actuator **96** which controls electrode deployment. In the present embodiment, the actuator **96** can comprise a solenoid **100**. As shown, the solenoid **100** is coupled to the control and power module **92** at a proximal end via a cable **105**, and coupled to the proximal end of the electrode **14** at a distal end via a luer fitting **104**. The actuator **100** is held within an actuator housing **102**, which is coupled to the luer fitting **104**. The luer fitting **104** is sized and shaped to attach to the proximal end of the elongated housing **12** of the deflectable interstitial ablation device **10**. Alternatively, the luer fitting **104** may be sized and shaped to attach to a working channel of a flexible cystoscope for those applications in which cystoscopes are used. When the foot pedal **90** is depressed, current from the power source **92** is applied to the solenoid **100**, which forces the electrode **14** to deploy beyond the distal end of the elongated housing **12**. Other types of actuators such as a rotary motors and linear motors, as well as other electromechanical devices can be used to perform these functions as well. It is to be appreciated that, a number of foot pedals and actuators for activating a mechanical event can be interchangeably used to actuate the electrode **14**, or provide fluid delivery and temperature sensing at the treatment site.

The deflectable interstitial ablation device **10** of the invention provides many other features typically performed in ablation procedures. As briefly described above, the deflectable interstitial ablation device **10** can be coupled to a fluid source to permits delivery of fluid to the housing **12** or to an internal bore (not shown) formed in the electrode **14** such that fluid is dispensed near the treatment site for providing cooling or for enhancing ablation. In such an embodiment, the fluid, can be for example, an electrolytic fluid which increases the ablation area, or a fluid that provides therapeutic effects. In another embodiment, the elongated housing **12** can include a separate passageway suitable for fluid delivery. In both embodiments, fluid can be introduced through the luer port **36** (FIG. **1**A). In another embodiment, the solenoid can be coupled to a syringe for introducing fluid inside the elongated housing **12**. Application of current to the solenoid in this case would cause the syringe to discharge the fluid held within a fluid source into the elongated housing **12**.

In another embodiment, the deflectable interstitial ablation device **10** can include a temperature sensing system for measuring tissue temperature during the ablation procedure. In one detailed embodiment, the temperature sensing system can include a thermocouple disposed near the distal end of the electrode **14**, such as by being fixed at the distal end of the insulation sheath **40** that is fixed to the electrode **14**. In still another embodiment, the device **10** can include an impedance monitoring system in communication with the proximal end of the electrode **14**. The impedance monitoring system can measure impedance near the distal end of the electrode **14**. The interstitial ablation device can further employ a feedback system that uses the temperature and or the impedance data to control the delivery of RF energy to the electrode **14**. The control module **92** can, for example, include means for automatically adjusting the magnitude and duration of the abla-

tion energy delivered to the electrode in response to one or both of these parameters. The interstitial ablation system can also include a safety feature which cuts off the delivery of energy when the temperature or the impedance value exceeds a threshold value.

The deflectable interstitial ablation device **10** of the present invention does not require the use of an endoscope and therefore can be entirely disposable. The disposable device can attach to reusable eye piece and other equipment such as a light source, and a control and power source module. In an alternative embodiment, the imaging system **16** can be removed from the device **10** for subsequent reuse.

As shown and described, the present invention features an improved transurethral interstitial ablation apparatus and method for performing transurethral ablation. While the invention has been particularly shown and described with reference to specific preferred embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A deflectable interstitial thermal treatment device, comprising:

an elongated housing having a proximal end, a distal end, and a deflectable segment;

an electrode mounted within the elongated housing and deployable from a first position within the elongated housing to a second position a predetermined distance beyond the distal end of the elongated housing, the electrode having a flexible portion capable of deflecting with the deflectable segment of the elongated housing;

remote means for activating deployment of the electrode; and

a deflection system disposed within the elongated housing controlled by a handle-operable steering mechanism for controllably deflecting the deflectable segment of the elongated housing by any angle with respect to a longitudinal axis of the housing, the deflection system having a proximal end in communication with the handle-operable steering mechanism.

2. The medical device of claim **1**, wherein the deflectable segment deflects at an angle between 0 degrees and 180 degrees with respect to a longitudinal axis of the elongated housing.

3. The medical device of claim **1**, wherein the deflectable segment deflects at an angle between 90 and 180 degrees with respect to the longitudinal axis of the elongated housing.

4. The medical device of claim **1**, wherein the remote means comprises a foot pedal.

5. The medical device of claim **1**, wherein the electrode is surrounded by an insulation sheath.

6. The medical device of claim **5**, wherein the insulation sheath comprises a polymeric material.

7. The medical device of claim **5**, wherein the insulation sheath covers the proximal portion of the electrode extending beyond the distal end of the elongated housing.

8. The medical device of claim **1**, further comprising a control system in electrical communication with a proximal end of the electrode.

9. The medical device of claim **8**, further comprising a power source in communication with the control system.

10. The medical device of claim **9**, wherein a foot pedal activates delivery of energy from the power source to the electrode.

11. The medical device of claim **1**, wherein the elongated housing is in communication with a handle.

12. The medical advice device of claim **11**, wherein the handle comprises slots.

13. The medical device of claim **12**, wherein the slots comprise levers.

14. A method for treating tissue, comprising the steps of:

(a) inserting a deflectable interstitial thermal treatment device into a body lumen which provides access to the tissue, the deflectable interstitial thermal treatment device comprising:

an elongated housing having a proximal end, a distal end, and a deflectable segment;

an electrode mounted with the elongated housing and deployable from a first position within the elongated housing to a second position a predetermined distance beyond the distal end of the elongated housing, the electrode having a flexible portion capable of deflecting with the deflectable segment of the elongated housing;

remote means for activating deployment of the electrode; and

a deflection system disposed within the elongated housing controlled by a handle-operable steering mechanism for controllably deflecting the deflectable segment of the elongated housing by any angle with respect to a longitudinal axis of the housing, the deflection system having a proximal end in communication with the handle-operable steering mechanism;

(b) positioning the distal end of the elongated housing near the tissue;

(c) deflecting the deflectable segment of the elongated housing toward the tissue;

(d) deploying the electrode to a position a distal end of the electrode adjacent the tissue; and

(e) applying an energy to the electrode in an amount and for a duration sufficient to thermally treat the tissue.

15. The method of claim **14**, wherein the tissue is prostate tissue.

16. The method of claim **14**, wherein the remote means for activating deployment of the electrode comprises the stepping on a foot pedal.

17. The method of claim **16**, wherein the electrode is covered by an insulation sheath.

18. The method of claim **17**, wherein the insulation sheath covers a proximal portion of the electrode extending beyond the distal end of the elongated housing.

19. The method of claim **17**, wherein the insulation sheath is extended over the proximal portion of the electrode, thereby preventing the electrode from touching the walls of the lumen during insertion of the medical device.

20. The method of claim **16**, wherein the electrode penetrates a wall of the lumen when deployed.

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